UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,308	03/20/2001	L. Dudley Eirich	U 0016 OS/OAPT	2258

28249 7590 09/15/2004

DILWORTH & BARRESE, LLP
333 EARLE OVINGTON BLVD.
UNIONDALE, NY 11553

EXAMINER
LILLING, HERBERT J

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/812,308	EIRICH ET AL.	
	Examiner	Art Unit	
	HERBERT J LILLING	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *5,6 and 16-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *5,6 and 16-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *June 25, 2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 03, 2004 has been entered.

2. Claims 1-30 are pending in this application.

3. Claims 1-4, 7-15 are drawn to the elected invention.

Claims 5-6 and 16-30 have been withdrawn.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 7-15 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Picataggio et al U.S.5,648,247; Anderson et al U.S. 5,962,285; Turner U.S. 6,288,275 ; Ron et al U.S. 20030049821 or Mobley et al., U.S. 6,066,480.

Each of the references teaches the omega oxidation of a terminal methyl substituents with Candida strain of H5343 that is within the scope of the claimed language.

Picataggio et al U.S. U.S.5,648,247 teaches

> "The organic substrate can be any aliphatic compound wherein at least one of the terminal carbons is a methyl group and which has from about 4 to about 22 carbon atoms. Such compounds include alkanes, alkenes, alkynes, carboxylic acids and their esters, and arenes. Preferred substrates are alkanes having from about 4 to about 22 carbon atoms and fatty acids and their methyl or ethyl esters wherein the acyl portion contains from about 4 to about 22 carbon atoms. The most preferred substrates are dodecane, tridecane, tetradecane, oleic acid, methyl oleate, methyl palmitate, methyl palmitoleate and methyl myristate."

Anderson et al. U.S. 5,962,285 teaches :

> "Examples of organic substrates which can be used in the process according to the invention include but are not limited to internal olefins such as 2-pentene, 2-hexene, 3-hexene, 9-octadecene and the like; unsaturated carboxylic acids such as 2-hexenoic acid and esters thereof, oleic acid and esters thereof including a triglyceryl esters having a relatively high oleic acid content, erucic acid and esters thereof including triglyceryl esters having a relatively high erucic acid content, ricinoleic acid and esters thereof including triglyceryl esters having a relatively high ricinoleic acid content, linoleic acid and esters thereof including triglyceryl esters having a relatively high oleic acid content; unsaturated alcohols such as 3hexen-1-ol, 9-octadecen-1-ol and the like; unsaturated aldehydes such as 3hexen-1-al, 9-octadecen-1-al and the like. In addition to the above, the organic substrate which can be used in the process according to the invention include alicyclic compounds having at least one internal carbon--carbon double bond and at least one terminal methyl group, a terminal carboxyl group and/or a terminal functional group which is oxidizable to a carboxyl group by biooxidation. Examples of such compounds include but are not limited to 3,6-dimethyl-1,4-cyclohexadiene; 3-methylcyclohexene; 3-methyl-1,4-cyclohexadiene and the like."

Turner et al. U.S. 6,288,275 teaches:

"The organic substrate can be any aliphatic compound or mixtures thereof wherein at least one of the terminal carbons is a methyl group and which has from about 4 to about 22 carbon atoms. Such compounds include alkanes, alkenes, alkynes, carboxylic acids and their esters, and arenes. Preferred organic substrates are alkanes and carboxylic acids. Examples of suitable substrates include, but are not limited to, dodecane, tridecane, tetradecane, oleic acid, stearic acid, palmitic acid, myristic acid, methyl, ethyl or other esters of the aforementioned fatty acids and combinations thereof. When producing a dicarboxylic acid, the organic substrate is preferably a compound possessing one carboxyl group and one methyl group or is a compound possessing one methyl group and a functional group that can be at least partially hydrolyzed to a carboxyl group. Thus, the organic substrate can be any aliphatic saturated or unsaturated monocarboxylic acid with a terminal methyl group except formic acid and acrylic acid. The organic substrate can also be an aromatic monocarboxylic acid possessing a methyl group, the simplest example of which is o, m, or p-methyl benzoic acid. Suitable monocarboxylic acids include, but are not limited to, oleic acid, stearic acid, palmitic acid, myristic acid, pelargonic acid, methyl benzoic acid and combinations thereof."

Ron et al U.S. 20030049821

Examples of unsaturated organic substrates which can be used herein include but are not limited to internal olefins such as 2-pentene, 2-hexene, 3-hexene, 9-octadecene and the like; unsaturated carboxylic acids such as 2-hexenoic acid and esters thereof, oleic acid and esters thereof including triglyceryl esters having a relatively high oleic acid content, erucic acid and esters thereof including triglyceryl esters having a relatively high erucic acid content, ricinoleic acid and esters thereof including triglyceryl esters having a relatively high ricinoleic acid content, linoleic acid and esters thereof including triglyceryl esters having a relatively high linoleic acid content; unsaturated alcohols such as 3-hexen-1-ol, 9-octadecen-1-ol and the like; unsaturated aldehydes such as 3-hexen-1-al, 9-octadecen-1-al and the like. In addition to the

above, an organic substrate which can be used herein include alicyclic compounds having at least one internal carbon-carbon double bond and at least one terminal methyl group, a terminal carboxyl group and/or a terminal functional group which is oxidizable to a carboxyl group by biooxidation. Examples of such compounds include but are not limited to 3,6-dimethyl, 1,4cyclohexadiene; 3-methylcyclohexene; 3-methyl-1, 4cyclohexadiene and the like.

Examples of the aromatic compounds that can be used herein include but are not limited to arenes such as o-, m-, .rho.-xylene; o-, m-, .rho.-methyl benzoic acid; dimethyl pyridine, and the like. The organic substrate can also contain other functional groups that are biooxidizable to carboxyl groups such as an aldehyde or alcohol group. The organic substrate can also contain other functional groups that are not biooxidizable to carboxyl groups and do not interfere with the biooxidation such as halogens, ethers, and the like.

Examples of saturated fatty acids which may be applied to cells incorporating the present CYP and CPR genes include caproic, enanthic, caprylic, pelargonic, capric, undecylic, lauric, myristic, pentadecanoic, palmitic, margaric, stearic, arachidic, behenic acids and combinations thereof. Examples of unsaturated fatty acids which may be applied to cells incorporating the present CYP and CPR genes include palmitoleic, oleic, erucic, linoleic, linolenic acids and combinations thereof. Alkanes and fractions of alkanes may be applied which include chain links from C12 to C24 in any combination. An example of a preferred fatty acid mixtures are Emersol.RTM. 267 and Tallow, both commercially available from Henkel Chemicals Group, Cincinnati, Ohio. The typical fatty acid composition of Emersol.RTM. 267 and Tallow is as follows:

Mobley et al., U.S. 6,066,480 teaches :

> Yeast produce diacids from fatty acids through the .omega.-oxidation pathway. The first and rate-limiting step is the oxidation of the terminal methyl carbon to produce an .omega.-hydroxy acid. This step is mediated by a membrane- bound enzyme complex consisting of a cytochrome P450 monooxygenase and an associated NADPH cytochrome reductase. Two additional enzymes, an alcohol oxidase and an aldehyde dehydrogenase, further oxidize the alcohol to create an .omega.-aldehyde acid and then the corresponding .alpha.,.omega.-dicarboxylic acid. Several yeasts are known to produce various diacids when grown on fatty acid, fatty acid ester, or alkane substrates, for example Candida tropicalis, C. albicans, C. cloacae, C. guillermondii, C. intermedia, C. lipolytica, C. maltosa, C. parapsilosis, and C. zeylenoides.

Each of the above references teaches the culturing of Candida species H5343 or eqivalent [Mobley et al] in a process that is considered to be within the claimed processes. If there are any differences with respect to the substrates, these differences would have been prima facie obvious to one of ordinary skilled in the art to employ a modification of substrates in view of the broad disclosure of the substrates as noted above absent unexpected or unobvious process conditions.

5. **No claim is allowed.**

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Examiner Lilling whose telephone number is 571-272-0918** and **Fax Number** is (703) 872-9306 or SPE Michael Wityshyn whose telephone number is 571-272-0926. Examiner can be reached Monday-Thursday from about 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit **1651**
September 14, 2004

Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651